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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,096	12/30/2003	Doddabele L. Madhavi	BIO 2-013	6934

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EXAMINER

FEDOWITZ, MATTHEW L

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/748,096

Applicant(s)

MADHAVI ET AL.

Examiner

Matthew L. Fedowitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-12, 15, 16, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 13, 14, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The amendment filed on January 24, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly.

#### ***Claim Objections***

The Objection to claim 5 has been withdrawn in view of applicant's amendment.

Claims 7-8, 13-14, 21 and 22 would be allowable if written independent form, however, since claims 7-8, 13-14, 21 and 22 depend from applicant's amendment to claims 6 and 10 which necessitate new grounds of rejection presented in this office action these claims are objected to.

#### ***Claim Rejections - 35 USC § 102***

I. The 35 U.S.C. §102(b) rejections of claims 1, 4, 5, 6, and 9 are maintained because the applicant's arguments are not persuasive.

A. Claim 1 is drawn to a water-dispersible, freeze-dried bioavailable coenzyme Q-10/ cyclodextrin complex. Iijima *et al.* teach a water dispersible freeze-dried bioavailable coenzyme Q-10/cyclodextrin complex (see English translation page 6 application example 2). Iijima *et al.* and the applicant's claim are directed to the same coenzyme Q-10. Since the applicant claims cyclodextrin complexes generally, the applicant is claiming the cyclodextrin complex as taught in Iijima *et al.*

B. Claim 4 is drawn to the complex of claim 1 where the cyclodextrin consists of  $\beta$ -cyclodextrin or  $\gamma$ -cyclodextrin. Iijima *et al.* teach the complex of  $\beta$ -cyclodextrin and coenzyme Q-10 complex (see English translation page 6 application example 2). The

applicant's claim of  $\beta$ -cyclodextrin is directed to a seven-unit cyclodextrin ring (hence the meaning of  $\beta$  as a prefix to cyclodextrin) and the  $\beta$ -cyclodextrin in the reference is a seven-unit ring as well.

C. Claim 5 recites a complex interpreted to be depending from claim 1 which is formulated into one or more of a topical preparation, a sublingual formulation, or for oral ingestion. Iijima *et al.* teach an oral and injectable bioavailable form of the coenzyme q-10/cyclodextrin complex (see English translation page 2 last paragraph). The oral preparation in Iijima *et al.* is seen to encompass both sublingual and orally ingested dosage forms because the applicant's claims do not demonstrate that the claimed complex exists in a dosage form that would differ from sublingual to oral administration. For example, a capsule would demonstrate oral ingestion and a quick dissolving tablet or gel would clearly demonstrate sublingual administration. The applicant though has provided no direction to show that the claimed invention is directed to a specific route when the prior art broadly teaches a coenzyme Q-10/cyclodextrin complex as an oral preparation.

D. Claim 6 is drawn to a method for making a water-dispersible complex, which comprises the steps of preparing a slurry of coenzyme Q-10 and cyclodextrin then drying the formulation by spray, vacuum or freeze drying. Iijima *et al.* teaches the same method where the differences are considered to be insignificant (see English translation page 6 application examples 1 and 2).

Applicant's amendment to claim 6 is rejected under 35 U.S.C. §102(b) because Iijima *et al.* teaches the same steps that the applicant claims (see English translation page 6 application examples 1).

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E. Claim 9 is drawn to the cyclodextrin of claim 6 being  $\beta$  or  $\gamma$ -cyclodextrin. Iijima *et al.* teach that the method for making the water-dispersible complex uses  $\beta$ -cyclodextrin (see English translation page 6 application examples 1 and 2). The applicant should note that the nomenclature for cyclodextrins consists of  $\alpha$ ,  $\beta$  and  $\gamma$ -cyclodextrins because the cyclodextrins consist of six, seven and eight units respectively.

II. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A. Claims 10-12, 15-16 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Iijima *et al.* Iijima *et al.* teaches a method of preparing a coenzyme Q-10 complex as described above (see English translation page 6 application examples 1 and 2). Iijima *et al.* also teaches that the coenzyme Q-10 complex is administered to an animal and ingested by said animal where the animal is a human (see English translation page 2 last paragraph). Further more, as stated above and in the previous office action Iijima *et al.* teach that the cyclodextrin to be used is a  $\beta$ -cyclodextrin as the applicant claims. And as stated previously, the complex is prepared by freeze-drying and for oral ingestion (see reference listed above)

### ***Claim Rejections - 35 USC § 103***

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

*Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As a result, the applicant's arguments have the following effect.

A. The 35 U.S.C. §103 rejections of claims 2, 3 and 4 are maintained because the applicant's arguments are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon a "vain attempt to reconstruct the invention in" hindsight, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

More specifically, the Patel citation is anything but a "vain attempt" to reconstruct the invention in hindsight because Patel states that one particular embodiment of the invention is a complex of an additive and an active ingredient (see column 28 lines 43-46). When defining what an additive is, cyclodextrin and cyclodextrin derivatives are taught (see column 32 lines 50-51 and when defining what active ingredients are, coenzyme Q-10 is listed as a preferred active ingredient (see column 6 line 39).

B. The 35 U.S.C. §103 rejections of claims 7, 8 and 9 are withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The 35 U.S.C. § 112 2<sup>nd</sup> paragraph rejection of claim 10-17 are withdrawn in view of applicant's amendment.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 refers to claim 17, which has been cancelled. Therefore it is unclear as to what is being claimed

### *Conclusion*

Applicant's amendments necessitate new ground(s) of rejection presented in this office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Matthew L. Fedowitz, Pharm.D., J.D.  
April 8, 2005

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James O. Wilson  
Supervisory Patent Examiner  
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